REMARKS

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 13 to 23, the only claims pending and currently under examination in this application.

The Examiner has first objected to the title, asserting that it is not description of the subject invention to which the claims are directed. The title reads: "Arrays Having Background Features and Methods for Using the Same." The claims that are currently being prosecuted are directed to methods of performing array assays using arrays having background features are employed. As such, it is respectfully submitted that the title is descriptive of the invention to which the claims are directed and the Examiner is respectfully requested to withdraw this objection.

Next, Claims 13-23 were rejected under 35 U.S.C. § 112, 1st ¶ for the asserted reason that the specification is non-enabling for these claims.

In making the above enablement rejection, the Examiner has specifically asserted that Claim 22 raises an issue of enablement because it includes SEQ ID NO:08, which sequence is the exact complement of a known human sequence, i.e., human p53. Because it is the exact complement, the Examiner is unclear as to how this sequence can serve as a background feature.

However, SEQ ID NO:08 is a specific embodiment of the class of background features referred to collectively in the specification as "empirically observed inactive probes." These probes are probes that, based on sequence alone, would be expected to bind their complementary target but are empirically observed to not bind to their complement. SEQ ID NO:08 was discovered by the Applicant as reported in Example 1 of the specification. In relevant part, Example 1 reads:

> The features that yielded minimal signal (labeled as Background Features in Figures 1 and 2) were tested on multiple arrays for their ability to hybridize to their specific labeled G3PDH cRNA target and in all cases were found to yield minimal signal. These empirically observed background probes are shown in

Table 1. Additionally, probes that were designed to hybridize to cRNA of a portion of the P53 gene (human tumor suppressor p53 gene; target polynucleotide (SEQ ID NO: 4) is the Watson-Crick complement of the mRNA) and those found to yield minimal signal with R6G-labeled P53 cRNA (SEQ ID NO:4) are also shown in Table 1.

As such, these sequences are good background features because they are empirically observed to be inactive, even though based on sequence information alone they would be expected to bind to their complementary sequence. It is hoped that the above explanation clarifies how Claim 22 does not in fact raise a question of enablement because SEQ ID NO:08 is a specific example of an empirically observed inactive probe, which is a type of background probe that may be employed in the subject methods.

It is also asserted that specification is not enabling because the claimed method places no limitation on the number, density, length and nucleotide composition of the various hybridization features and background features, as well as on the heterogeneity of the sample that is contacted therewith.

In response, it is respectfully submitted that the full scope of the claim is enabled when read in view of the specification.

In support of the pending claims, the specification provides extensive generic description of the background features. See e.g., paragraph 64; and paragraphs 88 to 95. The specification also provides extensive description of specific types of background features. In addition, working exemplification showing actual use of a number, e.g., 28 different probes (SEQ ID NOs:01 to 53), of specific background features is provided in the specification. As such, the specification provides both an extensive generic description of what a background probe is, as well as 53 specific representative background probes and shows the use of these 53 specific representative background probes.

Furthermore, the specification provides extensive written description of suitable types of probe/array configurations in general that can be employed in the subject methods, as well as specific representative embodiments thereof. See for example the general description of hybridization probes appearing at, among other locations, paragraph 59, and the supporting description of representative nucleic acids that may be employed as probes,

appearing at, among other locations, paragraphs 46 to 54. See also paragraph 61 which provides ranges for the lengths of the probes. Density of representative arrays is discussed in paragraph 70.

The specification also provides a full description of the sample and hybridization conditions that are employed in the subject assays. For example, the sample is described in paragraph 56, among other locations. Furthermore, the hybridization conditions recited in the claims are discussed in the specification at paragraphs 110 to 113, as well as paragraph 78. The working exemplification also provides a report of specific hybridization conditions in which the arrays having background features were actually employed and shown to work as claimed. See e.g., the Experimental Section. As such, the specification provides both a generic teaching of suitable hybridization conditions and specification representative hybridization conditions shown to work as claimed.

As such, it is respectfully submitted that Claims 13-23 are fully enabled by the specification because, when read in view of the specification and coupled with the knowledge of one of skill in the art, one of skill in the art would not have to practice undue experimentation in order to practice the full scope of the claimed invention.

Finally, Claims 13 to 23 were rejected under 35 U.S.C. § 112, 2nd ¶ for use of the term "stringent" in Claim 13, and the terms "substantially" in and "empirically observed inactive probes" in Claim 21.

With respect to the term "stringent" as used in Claim 13, the specification teaches:

> An example of stringent hybridization conditions is hybridization at 50°C or higher and 0.1×SSC (15 mM sodium chloride/1.5 mM sodium citrate). Another example of stringent hybridization conditions is overnight incubation at 42°C in a solution: 50 % formamide, 5 × SSC (150 mM NaCl, 15 mM trisodium citrate), 50 mM sodium phosphate (pH7.6), 5 × Denhardt's solution, 10% dextran sulfate, and 20 μg/ml denatured, sheared salmon sperm DNA, followed by washing the filters in 0.1 × SSC at about 65°C. Stringent hybridization conditions are hybridization conditions that are at least as stringent as the above representative conditions.

As such, the term "stringent," when read in view of the specification, would not render the claims indefinite to those of skill in the art.

With respect to the term "substantially" in Claim 21, solely in order to expedite prosecution and without in any way agreeing with the position of the Office, this term has

been removed from the claim.

Finally, with respect to the term "empirically observed inactive probes," the specification reads in part:

> Examples of empirically observed inactive probes are shown in Table 1, *infra*. In particular, these probes have been observed to bind their complementary targets very minimally, yielding minimal signal levels in hybridization assays and as such are useful as background probes in the methods of the subject invention. The probes shown in Table 1 are from sequences originally designed to bind human G3PDH (SEQ ID NO: 1) and P53 (SEQ ID NO: 4) targets. When the probes were allowed to hybridize to their complementary specific targets, very poor binding was observed. Subsequently, other purified targets, as well as complex pool RNA, were also observed to bind very poorly to these probes. Paragraph 89.

As such, the term "empirically observed inactive probes" when read in view of the specification, would not render the claims indefinite to those of skill in the art.

Accordingly, it is respectfully submitted that the rejection of Claims 13 to 23 under 35 U.S.C. § 112, 2nd ¶ may be withdrawn.

CONCLUSION

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,

Date: 5·12·03

By: _____

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